

(c) *Conditions of use.* (1) The drug is used for reducing excessive smooth muscle contractions, such as occur in urethral spasms associated with urolithiasis in cats and dogs and in colic spasms in horses.<sup>1</sup>

(2) It is administered intramuscularly or intravenously to dogs and cats at a level of 1 to 2 milligrams per pound of body weight. It is administered intramuscularly or intravenously to horses at a level of 0.25 milligrams per pound of body weight. Dosage can be repeated every 12 hours, as indicated.<sup>1</sup>

(3) Not for use in animals intended for food purposes.<sup>1</sup>

(4) For use only by or on the order of a licensed veterinarian.<sup>1</sup>

[40 FR 13858, Mar. 27, 1975, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

**§ 522.88 Sterile amoxicillin trihydrate for suspension.**

(a)(1) *Specifications.* Each vial contains 3 grams of amoxicillin as the trihydrate. The powder is reconstituted with sterile water for injection USP to a concentration of 100 or 250 milligrams per milliliter for use as in paragraph (d) of this section.

(2) Each vial contains 25 grams of amoxicillin as the trihydrate. The powder is reconstituted with sterile water for injection USP to a concentration of 250 milligrams per milliliter for use as in paragraph (e).

(b) *Sponsor.* See 000069 in § 510.600(c) of this chapter.

(c) *Related tolerance.* See § 556.38 of this chapter.

(d) *Conditions of use in dogs and cats—*  
(1) *Amount.* 5 milligrams per pound of body weight daily.

(2) *Indications for use—*(i) *Dogs.* Treatment of infections caused by susceptible strains of organisms as follows: Respiratory infections (tonsillitis, tracheobronchitis) due to *Staphylococcus aureus*, *Streptococcus* spp., *Escherichia coli*, and *Proteus mirabilis*; genitourinary infections (cystitis) due to *S.*

*aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*; gastrointestinal infections (bacterial gastroenteritis) due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*; bacterial dermatitis due to *S. aureus*, *Streptococcus* spp., and *P. mirabilis*; soft tissue infections (abscesses, lacerations, and wounds), due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*.

(ii) *Cats.* Treatment of infections caused by susceptible strains of organisms as follows: Upper respiratory infections due to *S. aureus*, *Staphylococcus* spp., *Streptococcus* spp., *Hemophilus* spp., *E. coli*, *Pasteurella* spp., and *P. mirabilis*; genitourinary infections (cystitis) due to *S. aureus*, *Streptococcus* spp., *E. coli*, *P. mirabilis*, and *Corynebacterium* spp.; gastrointestinal infections due to *E. coli*, *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp.; skin and soft tissue infections (abscesses, lacerations, and wounds) due to *S. aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Pasteurella multocida*.

(3) *Limitations.* For use in dogs and cats only. Administer once daily for up to 5 days by intramuscular or subcutaneous injection. Continue treatment for 48 hours after the animal has become afebrile or asymptomatic. If no improvement is seen within 5 days, review the diagnosis and change therapy. As with all antibiotics, appropriate in vitro culturing susceptibility testing of samples taken before treatment should be conducted. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Condition of use. Cattle—*(1) *Amount.* 3 to 5 milligrams per pound of body weight once a day according to the animal being treated, the severity of infection, and the animal's response.

(2) *Indications for use.*—Treatment of diseases due to amoxicillin-susceptible organisms as follows: Respiratory tract infections (shipping fever, pneumonia) due to *P. multocida*, *P. hemolytica*, *Hemophilus* spp., *Staphylococcus* spp., and *Streptococcus* spp. and acute necrotic pododermatitis (foot rot) due to *Fusobacterium necrophorum*.

(3) *Limitations.* Administer once daily for up to 5 days by intramuscular or subcutaneous injection. Continue treatment for 48 to 72 hours after the

<sup>1</sup>These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

animal has become afebrile or asymptomatic. Do not continue treatment beyond 5 days. Treated animals must not be slaughtered for food during treatment and for 25 days after the last treatment. As with all antibiotics, appropriate in vitro culturing and susceptibility testing of samples taken before treatment should be conducted. Milk from treated cows must not be used for human consumption during treatment or for 96 hours (8 milkings) after last treatment. Maximum volume per injection should not exceed 30 milliliters. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37330, Aug. 18, 1992; 60 FR 55659, Nov. 2, 1995]

**§ 522.90 Ampicillin implantation and injectible dosage forms.**

**§ 522.90a Ampicillin trihydrate sterile suspension.**

(a) *Specifications.* Each milliliter contains ampicillin trihydrate equivalent to 200 milligrams of ampicillin.

(1) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(2) *Related tolerances.* See § 556.40 of this chapter.

(3) *Conditions of use—(i) Calves.*

(A) *Amount.* For enteritis: 3 milligrams per pound of body weight, intramuscularly, once or twice daily, for up to 3 days. For pneumonia: 3 milligrams per pound of body weight, intramuscularly, twice daily, for up to 3 days.

(B) *Indications for use.* Treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella* spp. susceptible to ampicillin.

(C) *Limitations.* Not for use in other animals raised for food production. Treated animals must not be slaughtered for food use during treatment or for 9 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) *Dogs.* (A) *Amount.* 3 to 6 milligrams per pound of body weight intramuscularly, once or twice daily.

(B) *Indications for use.* Treatment of respiratory tract infections due to *E. coli*, *Pseudomonas* spp., *Proteus* spp.,

*Staphylococcus* spp., and *Streptococcus* spp.; tonsillitis due to *E. coli*, *Pseudomonas* spp., *Streptococcus* spp., and *Staphylococcus* spp.; generalized infections (septicemia) associated with abscesses, lacerations, and wounds due to *Staphylococcus* spp. and *Streptococcus* spp.

(C) *Limitations.* Continue treatment at least 48 hours after the animal's temperature has returned to normal and other signs of infection have subsided. Usual treatment is 3 to 5 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iii) *Cats.* (A) *Amount.* 5 to 10 milligrams per pound of body weight intramuscularly or subcutaneously, once or twice daily.

(B) *Indications for use.* Treatment of generalized infections (septicemia) associated with abscesses, lacerations, and wounds due to *Staphylococcus* spp., *Streptococcus* spp., and *Pasteurella* spp.

(C) *Limitations.* Continue treatment at least 48 hours after the animal's temperature has returned to normal and other signs of infection have subsided. Usual treatment is 3 to 5 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iv) *Swine.* (A) *Amount.* 3 milligrams per pound of body weight, intramuscularly, once or twice daily, for up to 3 days.

(B) *Indications for use.* Treatment of bacterial enteritis (colibacillosis) caused by *E. coli* and bacterial pneumonia caused by *Pasteurella* spp. susceptible to ampicillin.

(C) *Limitations.* Treated animals must not be slaughtered for food use during treatment or for 15 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b) *Specifications.* Each milliliter contains ampicillin trihydrate equivalent to 150 milligrams of ampicillin.

(1) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(2) *Related tolerances.* See § 556.40 of this chapter.

(3) *Conditions of use. Dogs—(i) Amount.* 3 to 5 milligrams of ampicillin per pound of body weight, once a day for up to 4 days.